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1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/623,268	FILSER ET AL.	
	Examiner	Art Unit	
	JASON L. LAZORCIK	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-34 and 41-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-34 and 41-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants reply dated January 12, 2009 presents claims 16-34 and 41-43 without amendment and in the identical form to Applicants reply dated November 15, 2007. The instant reply further adds new claims 44-46.

Claim 44 is substantially identical to independent claim 16 with the additional recited limitation in lines 16-19 such that "a positive model reflecting incompletely a situation in a patient's mouth is supplemented with regard to the three-dimensional outer and inner surfaces by computer technology". Applicant states that support for this limitation can be found on page 4, lines 7-12 of Applicants Specification.

Claim 45 is substantially identical to independent claim 16 with the additional recited limitation in step (3), lines 13-16 of "applying data for the enlargement factor (f) to be detectable optically, electromagnetically or mechanically-tactile on the blank, an attachment label or a package leaflet" and in step (5), lines 20-23 of "by use of an identification system, reading the data for the enlargement factor (f) applied on the blank, the attachment label or the packaging leaflet". Applicant states that Support for the instant limitation can be found on page 8, lines 22-26 of the Specification.

Claim 46 is substantially identical to independent claim 16 with the additional recited limitation in step (1), lines 5-7 of "removing an outer layer of the blank of porous ceramic material selected in step (1) in order to remove any existing density gradients in an outer material shell". Applicant states that support for the instant limitation may be found on page 13, lines 35-38.

Claims 1-15 and 35 to 40 have been previously cancelled and no claims have been withdrawn from consideration.

Therefore, claims 16-34 and 41-46 are pending for prosecution on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-34, 41-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlwend (US 6,106,747) in view of Applicant's Exhibit A: the John Halloran letter dated 6 April 2004 (supplied to the PTO in the response of 5/3/2004).

Wohlwend teaches (Column 1, lines 55-65) a method for forming dental prostheses having precise dimensions. In general, the reference teaches that a form for the prosthetic is "profiled" from a prepared block of material by cutting the desired shape in enlarged dimensions to "compensate for shrinkage during sintering". This enlarged form is subsequently sintered to the density and hardness required for the end use application.

The specific process disclosed by Wohlwend (Column 3, lines 24-42 and Column 4, lines 51-54) includes the steps of:

1. Processing ceramic to form a "homogeneous" blank of ceramic material (see Column 3, lines 45-63; claim 3, and claim 5) from powdered ceramic materials
2. Scanning and digitizing the dimensions of a positive model of a skeletal structure (Column 3, Lines 34-38);
3. Enlarging the dimensions of the model by "the appropriate enlargement factor" (Column 3, lines 40-43);
4. Transferring the enlarged dimensions to a porous ceramic blank via material removal (Column 3, Lines 40-42 and col. 3, lines 54-60)
5. Dense sintering the blank; and (Column 1, Lines 63-65, Claim 1,and Claim 7)
6. Facing the blank with a coating material (Column 4, lines 48-58).

Although Wohlwend does not explicitly teach "linearly" enlarging the dimensions "in all directions" as claimed, the reference does disclose applying the enlargement factor to the digitized prosthetic dimensions in order to "compensate for shrinkage during sintering". One of ordinary skill in the art equipped with the Wohlwend teachings would either find the linear compensation an implicit component of the instant reference or would alternatively recognize said "linear" enlargement "in all directions" as a merely obvious extension over the prior art.

Wohlwend does not explicitly limit the enlargement factor to conform the formula presented in Claims 16, 32, and 33.

It is instructive here to examine the Applicants enlargement factor to understand its intuitive and obvious mathematical basis. First Applicant teaches a material density prior to sintering, ρr or "the relative density, and a post-sintering density, ρs or "the achievable relative density". Assuming conservation of mass, the fraction $\rho s/\rho r$ is simply a mathematical representation for fractional volume shrinkage for the ceramic body from the pre-sintering stage to the post-sintering stage. The cube root of the volume ratio merely reduces the volumetric contraction ($\rho s/\rho r$) into a linear vector quantity which one of ordinary skill would recognize an obvious and natural form for scaling a digital representation (read x,y,z coordinates) of a volumetric body. Restated, although Wohlwend does not explicitly set forth the details of Applicants claimed enlargement factor, said enlargement factor details appear on their face to merely state an obvious solution to the enlargement operation contemplated and disclosed by Wohlwend.

The Halloran letter teaches the level of ordinary skill in the art at the time of the invention with respect to ceramic shrinkage during sintering and specifically the ordinary level of skill with respect to the "enlargement factor". To this end, Halloran explicitly states;

a. Ceramic engineers *routinely consider the shrinkage during fabrication*…moulds, tools, CAD dims, etc. are routinely made larger by "enlargement factors"…*This is a normal part of the ceramic art*, and *need not be specified in detail*.
b. Also well known in the art…the *enlargement factor is computed from starting density and sintered density*.
c. *It is commonly understood* that the reproducibility of the dimensions of the finished ceramic article depends upon the starting density, so *efforts are made to control this factor as part of the ordinary practice of ceramic manufacture*.

In short, Halloran teaches that it is a merely routine operation for a skilled ceramic engineer to compute enlargement factors by taking into account the starting density ("relative density") and final density ("achievable relative density") of a ceramic material. Further, one having an ordinary level of skill in the art would necessarily undertake steps to "control" the precision (e.g. calculating f to 4 decimal places) of the enlargement factor as a routine quality control measure to insure "the reproducibility of the dimensions of the finished ceramic article". Finally and most importantly, Halloran instructs that the calculation of "enlargement factors" are such a trivial matter and so notoriously well known in the art that they "need not be specified in detail".

Therefore, although Wohlwend may not specify the particular details of the enlargement factor as claimed by Applicant, the Halloran letter teaches that the claimed enlargement factor is a merely obvious extension over the prior art. Specifically, Halloran discloses that calculation of the enlargement factor is a "normal part of the ceramic art" and "need not be specified in detail". It follows that Applicants explicit rendering of these calculation details is insufficient to patentably distinguish the claimed invention over method disclosed in the prior art.

Similarly, the Wohlwend reference teaches a single iteration of the disclosed steps for fabricating a single tooth. Although the Wohlwend reference does not expressly require repeating all process steps for each artificial tooth substitute to be produced, such a repeated process would clearly fall within the purview of a skilled practitioner in the arts. Specifically, one of ordinary skill in the arts would be motivated to repeat all process steps including, *inter alia*, a step of calculating the enlargement factor as a routing quality control initiative. Restated, where the Wohlwend reference teaches essentially every feature of Applicants claimed process, an explicit requirement to repeat all of said steps would represent a trivial extension over the prior art for one of ordinary skill in the arts.

The Examiners position on this matter is supported by the Halloran letter which states in part that the engineers "*routinely consider the shrinkage during fabrication*", and that such a factor is "Also well known in the art…(and) *computed from starting*

density and sintered density". Finally, Halloran indicates that controlling the enlargement factor is *" part of the ordinary practice of ceramic manufacture".*

With respect to newly presented **Claim 45**, the prior art of record is silent regarding a step wherein data for the enlargement factor (f), to be detectable optically, electromagnetically or mechanically-tactile, is applied on the blank, an attachment label or a package leaflet and wherein an identification system reads the data applied on the blank.

Regarding the instant limitation, Applicant will appreciate that the use of labeling and information reading systems are notoriously well known in manufacturing and retail environments. Industrial inventory management systems are replete with examples wherein a material or product is labeled with identifying or other useful information and an information reading system is utilized to automate or otherwise facilitate a processing of the product information. For example, barcode systems are routinely employed in nearly every modern retail setting wherein a barcode or tag containing, inter alia, a products identity as well as additional information such as price per unit is attached to a product. This tagging system is typically paired with an information reading system which automates data entry and facilitates subsequent data processing. Similar labeling and information retrieval systems are further contemplated for labeling of workpieces and tools in product manufacturing environments (see for example Hewkin et. al., IEE review, (1989), pp. 203-206)

In short, Applicants recited application of processing data to an individual workpiece and the use of an identification system for reading said data is notoriously old in the art. Although the prior art is silent regarding application of such a system to the manufacture of dental prosthetics, such a protocol does not patentably distinguish the claimed invention in view of the ordinary level of skill in the art at the time of the invention. Although the above noted exemplary applications of such labeling technologies are not directly employed in dental prosthetic manufacture, a known work in one field may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. In the instant case, one of ordinary skill would have been motivated to make such a modification in order to achieve increased product reliability, to enhance product throughput, and to reduce probability of production errors. It follows therefore that Applicants recited method constitutes no more than application of a known technique, namely inclusion of a workpiece labeling and label reading method, to a known method for manufacturing dental prosthetics which is ready for improvement to yield a wholly predictable result.

3. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlwend (US 6,106,747) and the John Halloran letter as applied to Claim 1 above in further view of Guiot et. al. (US 6,287,121).

The prior art of record is silent regarding a step wherein " a positive model reflecting incompletely a situation in a patients mouth is supplemented with regard to the three-dimensional outer and inner surfaces by computer technology"

Regarding the newly recited limitations in Claim 44, Applicants Specification states that a negative model of the situation in a patients mouth is produced which in turn is used to produce a positive model." This passage continues by acknowledging that "This procedure is known and is used in dental technical practice", and that "the process according to the invention follows this known preliminary stage and digitizes completely the outer and inner surface of the skeletal structure model or the surface on the positive model.

Regarding the recited steps of digitizing and supplementing the digital model with "computer technology", Applicants Specification states that "Processes for digitization in the mouth of a patient on a prepared dental stump or a model are known for example from US, A 418312 (mechanical) and EP, B1 0054785 (optical)".

Although the excerpts from Applicants originally filed Specification are construed as an admission that each step of the formation of a positive model, and 2) digitization of said model, including the step of supplementation by computer technology, are known and conventional techniques in the art, Applicants recited method is made explicit in the United States patent to Guiot et. al. (US 6,287121).

Guiot is directed to a method for preparation of dental prosthesis comprising steps of formation of a positive model of a patient's teeth and digitization of that model for subsequent machining of the prosthetic. The reference explicitly recognizes (col. 3, lines 44-60) that the conventional modeling techniques result in inaccuracies or a model which reflects incompletely the situation in a patient's mouth. In response, Guiot teaches that it is known to supplement this computer data with individual duplicate sections of inner or outer surfaces in order to achieve a more accurate digital representation of the situation in the patient's mouth (col. 3, line 61- col. 4, line15). In view of the Guiot reference, one of ordinary skill in the art would have found it obvious to supplement an incomplete model of a patients mouth with additional data regarding the three dimensional outer and inner surfaces and to combine that data by way of computer technology as recited in claim 44, lines 16-19.

4. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlwend (US 6,106,747) and the John Halloran letter as applied to Claim 1 above in further view of Glass et. al. (Conference proceedings: American ceramic Society International Symposium on Manufacturing Practices and Technology, 5-8 Nov. 1995)

The prior art of record is silent regarding a step wherein an outer layer of the blank of porous ceramic material selected in step (1) is removed in order to remove any existing density gradients in an outer material shell.

Regarding the nature of density gradients in ceramic compacts, Glass states that "Density gradients created during forming (e.g. due to die wall friction) are undesirable as they promote differential or heterogeneous densification within the ceramic body, which often results in warping and cracking during sintering" (Glass - pg 2). Glass continues by noting that "The key to achieving a net-shape compaction process is to minimize or eliminate macroscopic density gradients in the particulate assembly during die filling and compaction" (pg 3 – Glass). Regarding the predictability of density distribution a pressed ceramic powder compact, Glass indicates that density distribution follows a predictable course (see figures 2 and 3 and page 4) with the highest densities in the top coroners, the lowest density in the bottom corners and that a radial gradient is established from "a high density at the edges to a lower density along the cylinder axis".

Glass explicitly recognizes that a homogeneous density profile is of primary importance to reducing warping and cracking during sintering. Further, the Glass reference makes plain that the density distribution in ceramic compacts vary in a known and predictable fashion with the noted formation of a high density outer shell on the ceramic compact. It follows that one having no more than an ordinary level of skill in the art would have been motivated to try Applicants recited step of "removing an outer layer

of the blank of porous ceramic material" in order to enhance the density homogeneity in the ceramic blank. That is, such a processing step, which removes a high density outer skin from the ceramic compact, would have constituted an obvious and predictable approach to "minimize or eliminate density gradients in the particulate assembly". Further, one of ordinary skill would have been motivated to remove the high density outer layer as a means to minimize differential or heterogeneous densification and to thereby minimize warping and cracking of the ceramic body during the sintering step.

Response to Arguments

Argument #1)

Applicant alleges that Wohlwend teaches the use of a purely empirical enlargement factor resulting in a "one-size fits all" parameter for similar blanks. Applicant alleges that this method is distinguished from the claimed invention wherein the enlargement factor is derived for each individual blank.

Argument #2)

Applicant alleges that Wohlwend does not disclose that the enlargement factor may be calculated on the base of a measurable parameter of the blank or that there is a relation between relative densities of the blank and the enlargement factor. Applicant thereby concludes that Wohlwend does not imply that there is a linear relationship between the enlargement factor and the shrinkage of the blank.

Argument #3)

Applicant alleges calculation of the enlargement factor according to the recited invention presupposes or assumes 1) conservation of mass and 2) a homogeneous starting material. Applicant alleges that these relationships have only been disclosed in the present application and that "in general, one has to assume a non-isotropic enlargement factor ". Applicant thereby concludes that the Examiner has employed impermissible hindsight reconstruction in framing the instant rejection.

5. Regarding Applicants arguments 1-3 directed exclusively against the Wohlwend reference, Applicant is respectfully advised that the rejection of claims is based upon the combined teachings to Wohlwend and Halloran under 35 U.S.C. §103(a). Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. Further, regarding Applicants allegation that Wohlwend fails to teach calculating the enlargement factor for each blank, Applicant is advised that mere duplication of process steps is prima facie obvious absent a compelling showing of unexpected results. To this end, calculating an enlargement factor for each individual blank amounts to no more than a routine quality control endeavor and such a protocol would

reasonably have been derived by a skilled technician seeking to enhance product reliability and repeatability.

Regarding Applicants additional arguments directed against Wohlwend, Applicant was previously advised that the Halloran letter teaches the level of ordinary skill in the art at the time of the invention with respect to ceramic shrinkage during sintering and specifically the ordinary level of skill with respect to the "enlargement factor". To this end, Halloran explicitly states;

> d. Ceramic engineers *routinely consider the shrinkage during fabrication*…moulds, tools, CAD dims, etc. are routinely made larger by "enlargement factors"…*This is a normal part of the ceramic art*, and *need not be specified in detail*.
> e. Also well known in the art…the *enlargement factor is computed from starting density and sintered density*.
> f. *It is commonly understood* that the reproducibility of the dimensions of the finished ceramic article depends upon the starting density, so *efforts are made to control this factor as part of the ordinary practice of ceramic manufacture*.

In short, Halloran teaches that it is a merely routine operation for a skilled ceramic engineer to compute enlargement factors by taking into account the starting density ("relative density") and final density ("achievable relative density") of a ceramic material. Most importantly, Halloran instructs that the calculation of "enlargement factors" are such a trivial matter and so notoriously well known in the art that they "need not be specified in detail".

In view of the foregoing, Applicants arguments alleging that the prior art fails to teach the theory of conservation of mass, the use of a homogeneous starting material,

or isotropic shrinkage of a ceramic preform during sintering are all considered moot. That is, since calculation of the enlargement factor is so notoriously well known in the art that the particulars "need not be specified in detail", each of the noted factors would reasonably be construed a routine consideration for calculation of an enlargement factor and said factors do not patentably distinguish the claimed invention over that disclosed in the prior art.

Argument #4)

Applicant alleges that the Halloran letter does not constitute prior art. With respect to this position, Applicant alleges that the Halloran letter can only be interpreted in view of the invention and that said letter "solely proves that a person skilled in the art is able to make and use the invention described in the patent application…Nothing more".

The Examiner agrees in part.

Applicant is correct in alleging that Halloran provides supporting basis such that one of ordinary skill would be able to make and use the invention described in the application, however Halloran goes well beyond merely stating that Applicants invention is enabled for one of ordinary skill. As noted above, Halloran explicitly states that calculation of the enlargement factor is a "normal part of the ceramic art" and is so "routine" an endeavor that its calculation "need not be specified in detail".

It will appear self evident that the Halloran letter constitutes far more than a mere statement of enablement for the disclosed invention. Rather, the Halloran letter, a

statement submitted by Applicant during prosecution of the instant case, is effective to establish the ordinary level of skill in the art at the time of the invention and as such said reference does constitute admitted prior art which may be relied upon for all that it teaches for determinations of anticipation and obviousness.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON L. LAZORCIK whose telephone number is (571)272-2217. The examiner can normally be reached on Monday through Friday 8:30 am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on (571) 272-1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven P. Griffin/
Supervisory Patent Examiner, Art Unit 1791

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